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PATENT
Attorney Docket No. 82906-667402 (011140US)
Client Ref. No. VX-1073-C1

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

Marc Odrich *et al.*

Application No.: 10/600,027

Filed: June 19, 2003

For: METHOD AND SYSTEMS FOR
LASER TREATMENT OF
PRESBYOPIA USING OFFSET
IMAGING

Confirmation No. 5696

Examiner: David M. Shay

Art Unit: 3769

REPLY BRIEF

Mail Stop Appeal Brief
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Commissioner:

Appellant offers this Reply Brief in furtherance of the Examiner's Answer mailed
March 29, 2011.

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1. STATUS OF CLAIMS

Claims 1-9 and 16-22 remain rejected and pending in the application.

2. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

Whether claims 1-9 and 16 were properly rejected under 35 U.S.C. 103(a) as being unpatentable over Frey in combination with Largent.

Whether claims 17-22 were properly rejected under 35 U.S.C. 103(a) as being unpatentable over Frey in combination with Largent.

3. ARGUMENT

The following facts, previously made of record by Appellants (e.g., Appeal Brief, pp. 7-9), ***do not appear disputed*** by the Examiner:

(1) Frey discloses determining only an ***outer diameter*** of an ablation zone to ensure that the dark-adapted pupil size does not exceed the ablation zone, so as to preclude night halos.

(2) Largent discloses applying a multifocal ablation zone, but Largent does not identify individual pupil size as factoring into the ablation.

(3) Even if combined, the combination of Frey and Largent would not explicitly teach adjusting ***multiple regions*** of an ablation profile (as opposed to adjusting ***only the outer diameter*** of the ablation zone) based on an individual patient's pupil size.

(4) Neither reference identifies any relationship between pupil size and inner or multiple regions of an ablation profile.

(5) Neither reference recognizes any relationship between pupil size and inner/multiple regions of an ablation profile as effecting vision correction or treatment of presbyopia.

The Examiner has not disputed that Frey and Largent, at least explicitly, fail to disclose each and every element of the claimed invention. Instead, the Examiner alleges that ordinary skill of the artisan indicates that treatment of presbyopia by scaling multiple regions of

an ablation profile based on pupil size would be inherently present in the cited references, thereby supplying those aspects of the currently claimed invention that are missing from the explicit teachings of Frey and Largent.¹ Unfortunately, the Examiner fails to provide sufficient evidence to support such an assertion. In fact, U.S. Patent No. 5,533,997 to Ruiz (hereafter “Ruiz”) provides significant evidence contrary to the Examiner’s assertions.

Ruiz was cited in an IDS filed 8/11/2003 and considered by the Examiner on 6/24/2005 (e.g., Office action mailed 7/25/2005). Ruiz is attached as Exhibit A.

Ruiz concerns performing presbyopia corrective surgery via corneal ablation. Ruiz mentions the pupil only as serving as a reference point for making a very central stromal ablation on the cornea (e.g., col. 3, ll. 8-10). Ruiz teaches a defined ablation zone on only a part of the middle portion of the cornea and having a specifically pre-determined diameter. Col. 1, ll. 15-17 states “[t]his simultaneous correction of near and distant vision is accomplished through use of just a part of the corneal surface (the middle).” Col. 3, ll. 24-26, stating “...an annular ablation is made on the stroma having a diameter not exceeding 3.5 mm, with a central zone varying between 2 and 3mm.” Col. 5, ll. 44-55, stating “[t]he diameter of this optical zone must be between about 2 and 3 mm” (emphasis added). Thus, Ruiz represents that the state of the art presbyopia corrective corneal ablation surgery included ablating only a middle part of the cornea with a central zone strictly defined as between 2 and 3mm in diameter, regardless of the patient’s individual pupil size.

In the Answer, the Examiner cites the following factors as supporting the allegation that missing aspects of Frey and Largent would have been well known to one of ordinary skill and inherent in the cited references:

- (1) Largent col. 1, ll. 57-59 stating “...tailored to suit the needs of the patient...” [Answer, p. 6];
- (2) Absence of discussion regarding pupil size in Largent [Answer, p. 6, ll. 21-24; p. 13, line 1 to p. 14, line 7];

¹ See, e.g., allegation that Appellants’ assertions “...are based on the premise of complete ignorance of one of ordinary skill in the art...” [Answer, p. 6, ll. 5-6]; “Thus there is ample evidence of record that the determination of the ratios of the various zones was well within the scope of one of ordinary skill in the art at the time of the invention...” [Answer, p. 7, ll. 2-4];

(3) Citation to previous decision by the Board regarding different claims, not currently pending in this appeal [Answer pp. 11-12].

Appellants will address each of the Examiner's identified factors in turn.

Turning first to Largent, the Examiner cites to col. 1, ll. 57-59 of Largent throughout the Answer (see, e.g., p. 6, ll. 19-21) to support the allegation that further modifications to the proposed combination of Frey/Largent, beyond what is explicitly disclosed in those references even if combined, would have been obvious. That cited provision of Largent provides the following:

[T]he specific configuration of the power curve across the cornea can be tailored to suit the needs of the patient and the particular design considerations.

However, the only "needs of the patient" identified in Largent are power correction needs - nothing beyond selecting power curve based on a prescribed vision correction power is identified.² Nothing at this cited provision, or elsewhere in the reference, addresses pupil size or scaling any aspect of the ablation profile based on pupil size. The fact that pupil size is mentioned *nowhere in Largent* suggests that, at that time, pupil size simply was not factored into the multi-zone correction of the type applied by Largent, as further supported by Ruiz. As Frey addresses only outer diameter of an ablation profile, Frey does not correct the deficiencies of Largent with respect to the currently pending claims.

The Examiner further alleges that Largent's complete silence regarding scaling inner/multiple ablation zones based pupil size actually indicates that this aspect was so well known that no discussion was needed in the reference. See, e.g., Answer, p. 6, ll. 21-24 stating "[t]hus clearly adjustment of all the curvature zones is contemplated in the disclosure of Largent, and is so well known to one of ordinary skill in the art that not even one example of how this would be accomplished is given." See also, p. 13, line 1 to p. 14, line 3, stating Appellants' "...argument is not convincing in view of the lack of any specific disclosure in Largent to

provide any specific ratio of the various regions, which clearly shows that this knowledge was in possession of one of ordinary skill in the art...”.

This argument by the Examiner is not well taken. First, the Examiner has not cited, nor do Appellants find, any authority indicating that mere silence of an art reference regarding a claim element/aspect indicates that the claim element in question is well known in the art. Such a position is unsupported by any authority governing patentability, and can be immediately dismissed at face value.

Second, given the robust prosecution history of the present case and continued focus on the Frey/Largent references, the Examiner should be able to cite some **objective evidence** demonstrating scaling inner/multiple ablation regions based on pupil size if such evidence were to exist at all.³ Yet, none has been cited. In fact, Ruiz provides evidence contradicting the Examiner’s assertions. While the Examiner did introduce, with virtually no discussion, U.S. Patent Nos. 5,182,238; 5,507,979; 5,530,491 in the 5/8/2010 Final Office Action (p. 9) as alleged showing inherency in the teachings of Largent, it appears that any reliance on those references has been abandoned as there is no reference to those patents in the Examiner’s Answer.⁴ Indeed, a review of those references and the provisions cited by the Examiner quickly reveals that the disclosures therein bear little, if any relevance, to the currently claimed invention. None of the ‘238, ‘979, or ‘491 patents concern corneal ablation at all, and none of those references disclose scaling of multiple optical zones based on individual pupil size. The ‘491 patent mentions a wearable lens portion having a size about half that of a pupil, but does not teach actually scaling an inner correction region based on an individual patient’s pupil size.

The reference to Ruiz does, in fact, concern corneal ablation for presbyopia corrective surgery, unlike the ‘238, ‘979, or ‘491 patents cited by the Examiner. As indicated above, Ruiz indicates that, prior to the present invention, presbyopia corrective corneal ablation

² See also, Largent col. 4, ll. 40-44, identifying only vision correction power.

³ The present application has been pending at the US Patent Office for nearly 8 years. The references to Frey and Largent were first cited by this Examiner nearly 6 years ago, and are now being considered by the Board for the second time in this case.

⁴ While Appellants believe those cited references lack relevancy to the issues at hand, Appellants object to their introduction upon closing prosecution by Final rejection, thereby denying Appellants opportunity to respond without the restrictions of response under 37 CFR §1.116.

surgery included ablating only a middle part of the cornea with a central zone strictly defined as between 2 and 3mm in diameter, regardless of the patient's individual pupil size.

The Examiner further presents a hypothetical scenario of a patient having such a small pupil size that ablation zones of Largent would be entirely omitted and result in a truncated ablation profile (Answer, p. 8, 2nd paragraph). However, the Examiner has presented no evidence that the Examiner's imagined scenario is a *realistic* one. There is no evidence in Largent or elsewhere that the Largent multi-zone profile is sized such that expected population variations in pupil size would present such a hypothetical scenario. In fact, Ruiz strictly defining a presbyopia corrective optical zone as having a diameter that must be between about 2 and 3 mm and cover only a middle part of the cornea suggests that the Examiner's scenario would not have been a realistic concern.⁵

Thus, the Examiner has failed to produce any objective evidence to support assertions of claim recited aspects being so well known in the art that they are inherent in Largent. Such a lack of evidence is particularly striking considering the some 6 years of prosecution focusing on the alleged teachings of Frey/Largent and Appellants repeated challenges to the Examiner's assertions.

Regarding the previous decisions by the Board of Appeals in the current case, Appellants' maintain, for at least the reasons previously made of record, that the Examiner's reliance on those Board decisions is misplaced. The Board previously considered the combination of Frey and Largent during prosecution of the current case. While *different* claims were rejected by the Board, current claims 1-9 were left in condition for allowance in view of Frey/Largent.

It is also noted that the Examiner has virtually ignored the Decision on Rehearing, (Exhibit B), which makes even more clear that rejection of the different claims 10-16 (not currently pending) was particular to the language of those claims. See, e.g., Decision on Rehearing, page 3, addressing the scope and content of Frey/Largent "...in the manner recited in

⁵ There is also no evidence that a patient with an abnormally small sized pupil would be in need of presbyopia treatment to begin with. For example, it is well known in optics that reducing aperture diameter increases depth of field (see, e.g., http://en.wikipedia.org/wiki/Depth_of_field).

claim 10” and “vis-à-vis claim 10”; Decision on Rehearing, page 5, stating “...in can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements *in the way the claimed invention does...*” (original emphasis); Decision on Rehearing, page 5, stating “...whether there was an apparent reason to combine the known elements *in the fashion claimed...*” (original emphasis); Decision on Rehearing, page 6, addressing the invention subject matter “...in the manner recited in claim 10...”

Appellants further note that the Examiner makes a number of inaccurate representations regarding the previous decisions by the Board. For example, p. 11, ll. 14-17 of the Answer, the Examiner states the following:

In reversing the examiner’s written description rejection, the Board explicitly stated that taking corneal healing into account ***was something that was within the scope of one of ordinary skill in the art*** (see the Decision, attached, the first full paragraph on page 10).
[emphasis added]

The Examiner’s above characterization is simply wrong, as no such statement (explicit or otherwise) was made by the Board. At page 10 of the Decision, the Board noted the Examiner’s confusion between the legal concepts of “written description” and “enablement” and further disagreed that one skilled in the art would be unable to make and use Appellants’ claimed invention per the enablement requirement of §112, first paragraph.

As the Answer contains a number of inaccuracies, it is worth stating explicitly that Appellants’ do not acquiesce to any representation made by the Examiner regarding Appellants previously stated positions or representations of previous decisions by the Board. Appellants believe that both the previous decisions by the Board and positions of record stated by Appellants speak for themselves.


4. CONCLUSION

For these reasons, it is respectfully submitted that the rejection should be reversed.

Respectfully submitted,

Dated: _____

5/27/2011



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5. EVIDENCE APPENDIX

- A. U.S. Patent No. 5,533,997 to Ruiz
- B. Decision on Request for Rehearing